

## REMARKS

### Summary of the Examiner's Actions

The examiner rejected Claims 1 and 13 under 35 U.S.C. § 102(b) as being anticipated by Cianci *et al.*, U.S. Patent Number 4,140,127. Applicant acknowledges the rejection under 35 U.S.C. § 102(b).

The examiner rejected Claims 2, 3, 14 and 15 under 35 U.S.C. § 103(a) as being obvious under Cianci *et al.*, in view of Wu *et al.*, U.S. Patent Number 4,246,909. Applicant acknowledges the rejection under 35 U.S.C. § 103(a).

The examiner rejected Claims 4 and 16 under 35 U.S.C. § 103(a) as being obvious under Cianci *et al.*, in view of Wu *et al.*, and Poncy, U.S. Patent Number 4,165,000. Applicant acknowledges the rejection under 35 U.S.C. § 103(a).

The examiner rejected Claims 5 and 17 under 35 U.S.C. § 103(a) as being obvious under Cianci *et al.*, in view of Poncy. Applicant acknowledges the rejection under 35 U.S.C. § 103(a).

The examiner rejected Claims 6 and 18 under 35 U.S.C. § 103(a) as being obvious under Cianci *et al.*, in view of Gammons *et al.*, U.S. Patent Number 6,224,543. Applicant acknowledges the rejection under 35 U.S.C. § 103(a).

The examiner rejected Claim 7 under 35 U.S.C. § 103(a) as being obvious under Cianci *et al.*, in view of Weaver, U.S. Patent Number 5,667,068. Applicant acknowledges the rejection under 35 U.S.C. § 103(a).

The examiner rejected Claims 8-10 under 35 U.S.C. § 103(a) as being obvious under Cianci *et al.*, in view of Poncy and further in view of Wu *et al.* Applicant acknowledges the rejection under 35 U.S.C. § 103(a).

The examiner rejected Claim 11 under 35 U.S.C. § 103(a) as being obvious under Cianci *et al.*, in view of Poncy and Wu *et al.*, and further in view of Gammons *et al.* Applicant acknowledges the rejection under 35 U.S.C. § 103(a).

The examiner rejected Claim 12 under 35 U.S.C. § 103(a) as being obvious under Cianci *et al.*, in view of Poncy and Wu *et al.*, and further in view of Weaver. Applicant acknowledges the rejection under 35 U.S.C. § 103(a).

#### **Rejections under 35 U.S.C. § 102(b)**

##### **1)      *The Law of Anticipation***

35 U.S.C. §102(b) states that "[a] person shall be entitled to a patent unless the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States." 35 U.S.C. §102(b) (2000). Section 2131 of the Manual of Patent Examining Procedure summarizes the standards for anticipation under 35 U.S.C. §102(b) as articulated by the United States Court of Appeals for the Federal Circuit. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim. *In re Bond*, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990).

##### **2)      *Claims 1 and 13***

##### **Examiner's Rejection**

The examiner rejected Claims 1 and 13 under 35 U.S.C. § 102(b) as being anticipated by Cianci *et al.*, U.S. Patent Number 4,140,127. In support of her rejection, the Examiner states:

Cianci discloses a catheter sheath having a first panel member 48a and a second panel member 48b defining a tubular configuration, the first panel being folded over to form a double thickness, and the second panel being folded over to form a double thickness (Col. 3, lines 30-40). See Fig. 2. Cianci inherently discloses the steps of providing a first panel 28a and a second panel 28b and folding the panels and heat sealing the panels to each other.

Applicant's Argument

Applicant respectfully disagrees with the examiner's reading of Cianci *et al.* Cianci *et al.*, disclose a sheath in which is disposed a catheter. The distal end of the sleeve is folded over to receive a user's fingers therein until the catheter is inserted into a patient. The distal end of the sheath is then unfolded to receive the penis of a patient. Because the user's hand was received under the folded distal end, when the sheath is unfolded the catheter and the penis are maintained in a sterile field. It is clear from the drawings and from the description thereof that the sheath disclosed by Cianci *et al.*, is structurally distinct - and therefore patentably distinct - from the present invention.

In the present invention, the two panel members are each folded over *prior to securing* to each other. In so doing, the first end of each panel permanently defines a double thickness. This construction provides several benefits. First, as disclosed in the specification in paragraph [0025], "[t]he construction of the first ends 128,138, namely by folding to provide a double thickness, furthers the ease of opening the first end opening 114 in the described manner."

The double thickness of the first end further assists in the restriction of the throat over the probe as it is inserted, thereby obviating the need for a retainer such as a rubber band, as discussed. Referring to paragraph [0006], a typical sheath such as that disclosed by Cianci *et al.*, is fabricated from a single thickness of film. This is insufficient to retain the sheath on the probe without assistance, such as a rubber band as illustrated in the prior art Figs. 1 and 2 of the present application. In the present invention, because the first end of the two panels are folded over to define the double

thickness prior to securement of the two panels, the overlapped portions are permanently formed into double layers, thereby providing the strength required to be retained on a probe unassisted.

Claim 1 of the present application sets forth in part:

... said first panel first end being folded over *prior to securement to said second panel member* to define a double thickness, and said second panel member first end being folded over *prior to securement to said first panel member* to define a double thickness

Claim 13 even more clearly sets forth the method for manufacturing this sheath, including the steps of:

- (a) providing a first panel member ...;
- (b) folding said first panel member first end under said first panel member;
- (c) positioning a second panel member ... over said first panel member;
- (d) folding said second panel member first end over said second panel member; and
- (e) securing said first panel member and said second panel member....

It is respectfully submitted that one skilled in the art would recognize that such would render the double thickness portions permanently secured in that manner. Once bonded, the double thickness portions could not be unfolded. On the contrary, it is clear that the distal end of the sheath is folded over only after the sheath is formed, and is unfolded as a step in its use. Accordingly, it is respectfully submitted that Cianci *et al.*, teach away from the present invention and, at the very least, do not anticipate the permanent securement of the distal end of the sheath in the folded configuration.

Accordingly, Applicant respectfully requests that the examiner reconsider and withdraw the rejections under 35 U.S.C. § 102(b).

Having no further objection to or rejection of Claims 1 and 13, it is respectfully submitted that such claims are in condition for allowance. Further, it is deemed that Claims 2-12, depending from Claim 1, and Claims 14-18, depending from Claim 13, are each in condition for allowance as depending from an allowable base claim.

**Rejections under 35 U.S.C. § 103(a)**

1)      *The Law of Obviousness*

35 U.S.C. §103(a) reads:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

35 U.S.C. §103(a) (2004).

A rejection under 35 U.S.C. § 103(a) must be supported by a *prima facie* case of obviousness. MPEP § 2142. Section 2143 of the Manual of Patent Examining Procedure summarizes the standards for a *prima facie* case of obviousness under 35 U.S.C. §103. The first element is that “there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings.” MPEP § 2143. The second element is that “there must be a reasonable expectation of success.” *Id.* The third element is that “the prior art reference (or references when combined) must teach or suggest all the claim limitations.” *Id.* The expectation of success and the motivation to combine the references “must both be found in the prior art, not in the applicants disclosure.” *In re Vaeck*, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

"There are three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art." *In re Rouffet*, 47 U.S.P.Q.2d 1453, 1457-58 (Fed. Cir. 1998) (The combination of the references taught every element of the claimed invention, however without a motivation to combine, a rejection based on a *prima facie* case of obvious was held improper); *see* MPEP § 2143.01. "Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight." *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999).

The standard of review applied to findings of fact is the "substantial evidence" standard under the Administrative Procedure Act (APA). *See In re Gartside*, 203 F.3d 1305, 1315, 53 U.S.P.Q.2d 1769, 1775 (Fed. Cir. 2000); *see also* MPEP 2144.03, pg. 2100-136, 8th ed., rev. 2. There must be some form of evidence in the record to support an assertion of common knowledge. *See In re Lee*, 277 F.3d 1338, 1344-45, 61 U.S.P.Q.2d 1430, 1434-35 (Fed. Cir. 2002); *In re Zurko*, 258 F.3d 1379, 1386, 59 U.S.P.Q.2d 1693, 1697 (Fed. Cir. 2001); *see also* MPEP 2144.03, pg. 2100-137, 8th ed., rev. 2. "With respect to core factual findings in a determination of patentability, however, the Board cannot simply reach conclusions based on its own understanding or experience -- or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings." *In re Zurko*, 258 F.3d 1379, 1386, 59 U.S.P.Q.2d 1693, 1697 (Fed. Cir. 2001).

The United States Supreme Court has held that the relevant facts for finding obviousness relate to (1) the scope and content of the prior art, (2) the level of ordinary skill in the field of the invention, (3) the differences between the claimed invention and the prior art, and (4) any objective evidence of nonobviousness such as long felt need, commercial success, the failure of others, or copying. *Graham v. John Deere Co.* 148

U.S.P.Q. 459, 467 (U.S. 1966). The *Graham* Court stated that “the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved.” *Id.* at 467. The *Graham* court further stated that “[s]uch secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy.” *Id.*

2)      *Claims 2, 3, 14 and 15*

Examiner's Rejection

The examiner rejected Claims 2, 3, 14 and 15 under 35 U.S.C. § 103(a) as being obvious under Cianci *et al.*, in view of Wu *et al.*, U.S. Patent Number 4,246,909. In support of her rejection, the Examiner states:

Claim 2 differs from Cianci in calling for the cover to further comprise a throat. Claim 3 differs in calling for the width of the throat to be less than one half of the circumference of the medical probe. Claims 14 and 15 differ in calling for the step of providing a throat with the specified circumference. Wu teaches a cover 10 for a medical probe having a throat 37 that has been heat sealed with a width that is less than one half of the circumference of the medical probe so that the cover cannot inadvertently slide off of the probe (Col. 3, lines 18-22, 43-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover of Cianci to have a throat of less than one half the circumference of the probe as taught by Wu so that the cover cannot inadvertently slide off of the probe.

Applicant's Argument

In view of the deemed allowability of independent Claims 1 and 13 above, it is deemed that Claims 2 and 3 are allowable as depending from allowable base Claim 1, and that Claims 14 and 15 are allowable as depending from allowable base Claim 13.

Notwithstanding the deemed allowability of the claims, Applicant respectfully disagrees with the examiner's reading of the Wu *et al.*, patent. Wu *et al.*, teach the receipt of a catheter 11 in the opening 37. In the illustrations, it is clear that the catheter is smaller than the opening such that the catheter may slide freely therein. In order to prevent the removal of the catheter, the catheter defines a bulbous end 20 dimensioned larger than the opening. To this extent, the bulbous end cannot be received within the opening.

In the present invention, as claimed in Claim 2, the throat is "adapted to closely receive a distal end of the medical probe." Then, as claimed in Claim 3, the throat is further adapted to define "a width adapted to be less than one-half the circumference of the medical probe distal end." As compared to Cianci *et al.*, which is configured to loosely receive a catheter and to *not* receive the catheter bulbous end, the present invention allows for the close receipt of a probe distal end, but is configured such that it restricts itself on the probe to prevent inadvertent removal. Claim 3 depends from Claim 2, both of which relate to a single element of the probe. However, to make the correlation of these claims to Cianci *et al.*, one must relate the two limitations to two distinct elements of the catheter.

Even in so doing, it is respectfully submitted that Cianci *et al.*, do not teach either. One element (the length of the catheter) is loosely received within the opening, as opposed to the claimed limitation of Claim 2 that the catheter distal end is "closely received." The other element (the bulbous end) is not received at all within the opening.

The analysis of Claims 14 and 15 follows that of Claims 2 and 3.

In view of the distinctions between the present invention and those elements of the cited prior art, it is respectfully submitted that there is no motivation for combining the prior art references to accomplish the present invention. Even if such motivation

were present, there is no reasonable expectation of success, as all of the elements of the present invention are not present in the cited prior art.

Accordingly, Applicant respectfully requests that the examiner reconsider and withdraw the rejections under 35 U.S.C. § 103(a).

3) *Claims 4 and 16*

Examiner's Rejection

The examiner rejected Claims 4 and 16 under 35 U.S.C. § 103(a) as being obvious under Cianci *et al.*, in view of Wu *et al.*, and Pancy, U.S. Patent Number 4,165,000. In support of her rejection, the Examiner states:

Claim 4 differs from Cianci in view of Wu in calling for the first end of the cover to define a funnel configuration. Claim 16 differs in calling for the step of defining the funnel. Pancy teaches a medical probe cover having a first end with a flaring or funnel configuration defined by a heat sealing die to facilitate the insertion of the medical probe (Col. 4, lines 18-22). See Fig. 5. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover above to have a first end with a funnel configuration as taught by Pancy to facilitate insertion of the probe.

Applicant's Argument

In view of the deemed allowability of independent Claims 1 and 13 above, it is deemed that Claim 4 is allowable as depending from allowable base Claim 1, and that Claim 16 is allowable as depending from allowable base Claim 13.

Notwithstanding the deemed allowability of the claims, for reasons set forth in the discussion of the Cianci *et al.*/Wu *et al.*, rejection, it is respectfully submitted that there is no motivation for combining the cited prior art references to accomplish the present invention as set forth in Claims 4 and 16. Even if such motivation were present, there is no reasonable expectation of success, as all of the elements of the present invention are not present in the cited prior art.

Accordingly, Applicant respectfully requests that the examiner reconsider and withdraw the rejections under 35 U.S.C. § 103(a).

4) *Claims 5 and 17*

Examiner's Rejection

The examiner rejected Claims 5 and 17 under 35 U.S.C. § 103(a) as being obvious under Cianci *et al.*, in view of Poncy. In support of her rejection, the Examiner states:

Claim 5 differs from Cianci in calling for the first panel member to extend beyond the second panel. Claim 17 differs in calling for the step of defining the extended portion. Poncy teaches a cover having a first panel 24 that projects beyond the end of the second panel 22 to serve as a guide to facilitate inserting the probe into the sheath (Col. 3, lines 60-63). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover of Cianci to have a first panel extending beyond the second panel as taught by Poncy to facilitate insertion of the probe into the sheath.

Applicant's Argument

In view of the deemed allowability of independent Claims 1 and 13 above, it is deemed that Claim 5 is allowable as depending from allowable base Claim 1, and that Claim 17 is allowable as depending from allowable base Claim 13.

Accordingly, Applicant respectfully requests that the examiner withdraw the rejections under 35 U.S.C. § 103(a).

5) *Claims 6 and 18*

Examiner's Rejection

The examiner rejected Claims 6 and 18 under 35 U.S.C. § 103(a) as being obvious under Cianci *et al.*, in view of Gammons *et al.*, U.S. Patent Number 6,224,543. In support of her rejection, the Examiner states:

Claim 6 differs from Cianci in calling for the cover to be partially inverted. Claim 18 differs in calling for the step of inverting the second end. Gammons teaches a sheath having a second end that has been inverted to facilitate

movement of the sheath onto the tip of a medical probe (Col. 1, lines 9-11). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover of Cianci to be partially inverted as taught by Gammons to facilitate movement of the sheath onto the tip of a medical probe.

Applicant's Argument

In view of the deemed allowability of independent Claims 1 and 13 above, it is deemed that Claim 6 is allowable as depending from allowable base Claim 1, and that Claim 18 is allowable as depending from allowable base Claim 13.

Accordingly, Applicant respectfully requests that the examiner withdraw the rejections under 35 U.S.C. § 103(a).

6)      *Claim 7*

Examiner's Rejection

The examiner rejected Claim 7 under 35 U.S.C. § 103(a) as being obvious under Cianci *et al.*, in view of Weaver, U.S. Patent Number 5,667,068. In support of her rejection, the Examiner states:

Claim 7 differs from Cianci in calling for the cover to be fabricated of a material having elastomeric properties. Weaver teaches a protective cover for a medical probe formed of an elastic material so that the cover can protect the delicate probe (Col. 2, lines 61 -66). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover of Cianci to be formed of an elastic material as taught by Weaver to protect the delicate probe.

Applicant's Argument

In view of the deemed allowability of independent Claim 1 above, it is deemed that Claim 7 is allowable as depending from allowable base Claim 1.

Accordingly, Applicant respectfully requests that the examiner withdraw the rejections under 35 U.S.C. § 103(a).

7) *Claims 8-10*

Examiner's Rejection

The examiner rejected Claims 8-10 under 35 U.S.C. § 103(a) as being obvious under Cianci *et al.*, in view of Poncy and further in view of Wu *et al.* In support of her rejection, the Examiner states:

Cianci discloses a catheter sheath having a first panel member 48a and a second panel member 48b defining a tubular configuration, the first panel being folded over to form a double thickness, and the second panel being folded over to form a double thickness (Col. 3, lines 30-40). See Fig. 2.

10. Claim 8 differs from Cianci in calling for the first panel member to extend beyond the second panel. Poncy teaches a cover having a first panel 24 that projects beyond the end of the second panel 22 to serve as a guide to facilitate inserting the probe into the sheath (Col. 3, lines 60-63). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover of Cianci to have a first panel extending beyond the second panel as taught by Poncy to facilitate insertion of the probe into the sheath.

11. Claim 8 further differs from Cianci in view of Poncy in calling for in calling for the cover to further comprise a throat. Claim 9 differs in calling for the width of the throat to be less than one half of the circumference of the medical probe, Wu teaches a cover 10 for a medical probe having a throat 37 with a width that is less than one half of the circumference of the medical probe so that the cover cannot inadvertently slide off of the probe (Col. 3, lines 18-22, 43-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover of Cianci to have a throat of less than one half the circumference of the probe as taught by Wu so that the cover cannot inadvertently slide off of the probe.

12. Claim 10 differs from the teachings above in calling for the cover to have a funnel configuration. Poncy teaches a medical probe cover having a first end with a flaring or funnel configuration to facilitate the insertion of the medical probe (Col. 4, lines 18-22). See Fig. 5. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover above to have a first end with a funnel configuration as taught by Poncy to facilitate insertion of the probe.

### Applicant's Argument

In view of the deemed allowability of independent Claim 1 above, it is deemed that Claims 8-10 are allowable as depending from allowable base Claim 1.

Notwithstanding the deemed allowability of the claims, for reasons set forth in the discussion of the Cianci *et al.*/Wu *et al.*/Poncy rejection above, it is respectfully submitted that there is no motivation for combining the cited prior art references to accomplish the present invention as set forth in Claims 8-10. Even if such motivation were present, there is no reasonable expectation of success, as all of the elements of the present invention are not present in the cited prior art.

Accordingly, Applicant respectfully requests that the examiner withdraw the rejections under 35 U.S.C. § 103(a).

8)      *Claim 11*

### Examiner's Rejection

The examiner rejected Claim 11 under 35 U.S.C. § 103(a) as being obvious under Cianci *et al.*, in view of Poncy and Wu *et al.*, and further in view of Gammons *et al.*. In support of her rejection, the Examiner states:

Claim 11 differs from the teachings above in calling for the cover to be partially inverted. Gammons teaches a sheath having a second end that is inverted to facilitate movement of the sheath onto the tip of a medical probe (Col. 1, lines 9-11). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover above to be partially invested as taught by Gammons to facilitate movement of the sheath onto the tip of a medical probe.

### Applicant's Argument

In view of the deemed allowability of independent Claim 1 above, it is deemed that Claim 11 is allowable as depending from allowable base Claim 1.

Accordingly, Applicant respectfully requests that the examiner withdraw the rejections under 35 U.S.C. § 103(a).

9) *Claim 12*

Examiner's Rejection

The examiner rejected Claim 12 under 35 U.S.C. § 103(a) as being obvious under Cianci *et al.*, in view of Poncy and Wu *et al.*, and further in view of Weaver. In support of her rejection, the Examiner states:

Claim 12 differs from the teachings above in calling for the cover to be fabricated of a material having elastomeric properties. Weaver teaches a protective cover for a medical probe formed of an elastic material so that the cover can protect the delicate probe (Col. 2, lines 61-66). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover above to be formed of an elastic material as taught by Weaver to protect the delicate probe.

Applicant's Argument

In view of the deemed allowability of independent Claim 1 above, it is deemed that Claim 12 is allowable as depending from allowable base Claim 1.

Accordingly, Applicant respectfully requests that the examiner withdraw the rejections under 35 U.S.C. § 103(a).

**Summary**

In view of the amendment of the arguments presented herein, it is believed that the above-identified patent application is in a condition for the issuance of a Notice of Allowance. Such action by the examiner is respectfully requested. If, however, the examiner is of the opinion that any of the drawings or other portions of the application are still not allowable, it will be appreciated if the examiner will telephone the undersigned to expedite the prosecution of the application.

Please charge any additional fees associated with this communication, or credit any overpayment, to Deposit Account No. 16-1910 (27455.00).

Respectfully submitted,

PITTS & BRITTIAN, P.C.

by: /Jeffrey N. Cutler/  
Jeffrey N. Cutler  
Registration Number 35,486

PITTS AND BRITTIAN, P.C.  
P.O. Box 51295  
Knoxville, Tennessee 37950-1295  
(865) 584-0105 Voice  
(865) 584-0104 Fax